REMARKS

Claims 1-29 are pending in the present application.

At the outset, Applicants wish to thank Examiner Chawla for providing a copy of the missing Wiley reference. Applicants would also like to thank Examiner Chawla and Examiner Hendricks for the helpful and courteous discussion with their undersigned representative on November 28, 2007. During this discussion several amendments and arguments to address the rejections under 35 U.S.C. §112 and over the prior art were discussed. The content of this discussion is reflected in and expanded upon in the following remarks. Reconsideration of the outstanding rejections is requested.

The rejection of Claims 5-16 under 35 U.S.C. §112, first paragraph (enablement), is obviated in part by amendment and traversed in part.

The Examiner has haled that the claims lack enablement due to the uncertainty of the phrase "at an amount approximating to a salt concentration not inhibiting the hydrolysis of the protein to form unrefined soy". Applicants make no statement with respect to the propriety of this ground of rejection and in no way acquiesce to the same. Nonetheless, to expedite examination of the claimed invention, Applicants have amended Claim 5 based on page 13, lines 15-17 to replace the objected to phrase with "at a sodium chloride concentration of 5% by weight or less". Applicants submit that the claims as currently presented, embracing the new phrase in place of the objected to phrase, are fully enabled by the present specification.

Withdrawal of this ground of rejection is requested.

The rejection of Claim 16 under 35 U.S.C. §112, first paragraph (written description), is respectfully traversed. With respect to the *Lactococcus lactis* FERM BP-08552 strain, Applicants submit that this strain was deposited in accordance with the Budapest Treaty with an appropriate despository (see Deposit receipt filed on December 9, 2003). Further, Applicants hereby state that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon granting of a patent on this application.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

The rejections of: (a) Claims 5-7 and 9-16 under 35 U.S.C. §103(a) over Baensch in view of Takebe; (b) Claim 8 under 35 U.S.C. §103(a) over Baensch in view of Takebe and Arnaud; and (c) Claims 11 and 12 under 35 U.S.C. §103(a) over Baensch in view of Takebe and Izumi, are respectfully traversed.

In the Office Action mailed August 24, 2007, the Examiner has taken the position that the claimed invention is obvious over Baensch in view of Takebe, with or without Arnaud and Izumi, we provide the following comments. Applicants disagree and submit that the combination of Baensch and Takebe do not render the presently claimed invention obvious even when combined with either Arnaud or Izumi.

Specifically, Applicants submit that the disclosure of Baensch is deficient on several fronts, including: (a) failure to disclose addition of lactic acid bacteria during step (i) and (ii); (b) failure to disclose the concentration of the lactic acid bacteria present during either step (i) or (ii); (c) failure to disclose the hydrolysis ratio of the seasoning; and (d) failure to disclose the concentration of isobutyl alcohol, n-butyl alcohol, isoamyl alcohol, and/or acetic acid in the seasoning. The Examiner alleges that Takebe compensates for (a) and (b), while (c) is

inherent, and (d) would be expected "since [Baensch] teaches of similar process as instantly claimed". Applicants disagree with the Examiner.

With respect to deficiency (a), Takebe does appear to provide some motivation to add lactic acid bacteria for both steps (i) and (ii), but such a suggestion merely provides a possible basis to perform the claimed method. Therefore, with respect to (a), even if the artisan were to combine the disclosure of Baensch with Takebe, the combination would provide and "invitation to experiment" or could be viewed as making it "obvious to try" to arrive at the present invention. However, "obvious to try" has long been held *not* to constitute obviousness. *In re O'Farrell*, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988). A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out. *In re Deuel*, 34 USPQ2d 1210, 1216 (Fed. Cir. 1995).

Some allege that *KSR* eliminates the "obvious to try" defense, but this is not the case. *KSR* clearly states that "obvious to try" may constitute obviousness, but only under certain circumstances. Specifically, *KSR* stated that the fact that a claimed combination of elements was "obvious to try" might show that such combination was obvious under 35 U.S.C. § 103, since, if there is design need or market pressure to solve problem, and there are finite number of identified, predictable solutions, person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. However, the Examiner offers nothing to show how these factors apply and whether there would be such an expectation or anticipated success.

The fact of the matter remains, there must be some reasonable expectation of success. To this end, "the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success." *In re Merck & Co., Inc.*, 800

F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Before even addressing the issue of reasonable expectation of success it must be noted that the foregoing only addresses deficiency (a) in Baensch. At least three other deficiencies remain, which further cut against the obviousness of the claimed invention.

In regard to deficiency (b), the Examiner cites Takebe as compensating for this deficiency (i.e., disclosing the concentration of the lactic acid bacteria present during either step (i) or (ii)). However, the Examiner appears to recognize that Takebe disclose addition of an inoculum having significantly less bacteria than the claimed concentration. The Examiner properly points out that Takebe disclose addition of an inoculum of 10^3 CFU per gram, which grows to 1.2×10^7 CFU per gram during preparation of koji, and further grows to between 2.2×10^9 to 3.4×10^9 CFU per gram during hydrolysis.

Despite the Examiner's recognition of the failure of the combined disclosures of Baensch and Takebe to disclose the claimed concentrations, the Examiner alleges that the concentration differences and modification to arrive at the claimed concentrations "would not have involved undue experimentation on the part of one of ordinary skill in the art at the time of the invention." On this basis, the Examiner alleges that it would be obvious to modify the amount of lactic acid bacteria to arrive at the claimed values. However, this allegation is misplaced on its own. It must be noted that the artisan is not simply making a close step or modification to arrive at the claimed invention. The fact remains that the artisan would first need to modify the disclosure of Baensch based on the disclosure of Takebe to allegedly arrive at addition of lactic acid bacteria for both steps (i) and (ii). Subsequently, the artisan would need to then modify the *combined disclosures* of Baensch and Takebe to increase the concentration of lactic acid bacteria by ***orders*** of magnitude to arrive at the claimed invention. Clearly this is beyond routine experimentation or obvious optimization.

Moreover, it is also notable that Baensch and Takebe fail to disclose the hydrolysis ratio of the seasoning (deficiency (c)) and the concentrations of isobutyl alcohol, n-butyl alcohol, isoamyl alcohol, and/or acetic acid in the seasoning (deficiency (d)). For the hydolysis ratio, the Examiner cites Wiley p. 2178. However, this reference does not appear to support the Examiner's conclusion.

On page 11, lines 1-3 of the specification the term "hydrolysis ratio to amino acids" is defined as the "ratio of *free amino acids* to the total amount of amino acids contained in the hydrolyzed solution." Wiley disclose that the use of defatted soybean instead of whole beans increases the "protein digestibility of raw materials from 65 to 95%". This disclosure by Wiley does not state what amount of the digested raw materials is "free amino acids". Further, lines 4-5 under the heading "Composition" in Wiley clearly indicate that lower peptides and peptones are present in addition to amino acids. This is important as "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) In this case, the Examiner has clearly failed to meet this burden.

With respect to deficiency (d), the Examiner's position is based on the "similarity" between the claimed method and the method disclosed by Baensch. However, for the reasons given above, Applicants submit that the claimed method and the method disclosed by Baensch are not "similar", but rather differ on several important fronts. Therefore, it is not

reasonable to conclude that the concentrations of isobutyl alcohol, n-butyl alcohol, isoamyl alcohol, and/or acetic acid in the seasoning would be achieved by the method disclosed by Baensch.

Arnaud is cited as disclosing that "extrusion cooking of defatted soy was known in the art at the time of the invention". And, Izumi is cited as disclosing "a method of making soy based seasoning where the fermentation of soy sauce takes place in large batches in a closed type tank in order to reduce the fermentation time of the soy based seasoning." Although reserving the right to do so later, Applicants make no statement with respect to the propriety of these assertions by the Examiner and make no statement as to the propriety of combining Arnaud and/or Izumi with Baensch and Takebe. However, Applicants do take this opportunity to note that even if the disclosures of Arnaud and/or Izumi are combined with Baensch and Takebe, the aforementioned deficiencies in the combined disclosures of Baensch and Takebe are not remedied.

Accordingly, for the reasons given above, withdrawal of these grounds of rejection is requested.

The rejection of Claims 5-16 under 35 U.S.C. §112, second paragraph, is obviated in part by amendment and traversed in part.

The Examiner has made a series of indefiniteness rejections alleging that several of the terms in the original claims lack clarity, lack antecedent basis, or are relative terms. Below is a summary of these criticisms and Applicants corresponding comments:

1) The Examiner alleges that the phrase "at an amount approximating to a salt concentration not inhibiting the hydrolysis of the protein to form unrefined soy and then fermenting the unrefined soy" in Claim 5, step (ii), is unclear for the following reasons:

   a. What is "unrefined soy"?

b. How does "unrefined soy" differ from "resulting solid koji"?

c. What solution is added to the solid koji (i.e., is it a salt solution or a sugar solution or a solution with one or more microorganisms?

d. What is the "amount approximating the salt concentration not inhibiting hydrolysis"?

e. What is the salt (i.e., common salt (sodium chloride), calcium salt, potassium salt, etc.)?

With respect to (a), Applicants submit that the claim clearly indicates that the "unrefined soy" is the product of hydrolysis of the vegetable protein contained in the "resulting solid koji" prepared in step (i). Also, the claims clearly set forth the differences between the "resulting solid koji" (product of step (i)) and the "unrefined soy" (product of the hydrolysis portion of step (ii)). Thus, criticisms (a) and (b) are without merit.

Applicants make no statement with respect to the propriety of criticisms (c) and (d) and in no way acquiesce to the same. Nonetheless, to expedite examination of the claimed invention, Applicants have amended Claim 5 based on page 13, lines 15-17 to replace the phrase "hydrolyzing the protein by adding a solution to the resulting solid koji at an amount approximating to a salt concentration not inhibiting the hydrolysis of the protein to form unrefined soy" with "hydrolyzing, at a salt concentration of 5% by weight or less, the protein in the resulting solid koji to form unrefined soy".

Finally, with respect to (e), Applicants have amended the claims based on Example 4 on page 24 of the specification to replace "salt" with "sodium chloride".

2) The Examiner alleges that it is unclear in Claim 5 if the alcohol and acetic acid concentrations are (a) requirements of the process (i..e., target concentrations at which point the process is stopped), (b) are characteristics of the final product, or (c) are added to the end product.

Applicants submit that the plain language of the claim:

> wherein *the seasoning* is at a hydrolysis ratio to amino acids at 65% or more; an isobutyl alcohol concentration at 0.1 mg per gram of nitrogen

> or less; an n-butyl alcohol concentration at 0.25 mg per gram of nitrogen or less; an isoamyl alcohol concentration at 0.5 mg per gram of nitrogen or less; and an acetic acid concentration at 100 mg per gram of nitrogen or less.

makes it clear that the alcohol and acetic acid concentrations are characteristics of the final product (i.e., proposed interpretation (b)). This interpretation is not only consistent with the original claim language, but also is clear from the Examples of the present application. Accordingly, Applicants submit that no amendment is necessary.

3) The Examiner alleges that it is unclear whether the percentage of salt in Claim 6 is measured in (a) the unrefined soy during the hydrolysis step, (b) before the fermentation step, or (c) after the fermentation step.

Based on the disclosure at page 15, lines 13-18, Applicants submit that it is clear that the salt concentration in original Claim 6 refers to the amount of salt measured in the unrefined soy before the fermentation step (i.e., possibility (b)). Accordingly, Applicants submit that no amendment is necessary.

4) The Examiner alleges that the term "raw material" in Claims 5, 7, and 8 is a relative term.

Applicants disagree with the Examiner's characterization of "raw material" as a "relative term". To this end, the Examiner is referred to the definition of the term "raw material" on page 11, lines 4-11 and page 12, lines 17-23. Thus, the meaning of this term is clearly defined and is definite. Accordingly, Applicants submit that no amendment is necessary.

5) The Examiner questions whether the time and temperature limitations (Claim 9) and the pH limitation (Claim 10) refer to the hydrolysis part of Claim 5, step (ii), or the fermentation part.

Applicants refer to page 15, line 14 of the specification, which clearly states that raw materials, such as defatted soybean, are hydrolyzed during the fermentation step. Therefore, the hydrolysis and fermentation occur during the same step and the time and temperature

limitations refer to the conditions for fermentation. Accordingly, Applicants submit that no amendment is necessary.

6) The Examiner alleges that Claims 11 and 12 are unclear for a number of reasons.

The specification at page 16, lines 10-14 clearly describes what is intended by these dependent claims (i.e., fermentation under a nitrogen atmosphere; see also Example 1 at page 18, lines 5-11). As stated above, hydrolysis occurs during fermentation. Therefore, when the claims are reviewed with the definitions provided in the specification, Applicants submit that the meaning of Claims 11 and 12 are clear. Accordingly, Applicants submit that no amendment is necessary.

7) The Examiner alleges that the phrase "protein hydrolysis potency" is unclear as it is not certain whether the microorganisms added to koji have protein hydrolysis potency (i.e., proteases, etc.) or external enzymes having protein hydrolysis potency have been added to the koji in addition to the microorganisms.

Applicants submit that this criticism is without merit as the claim clearly specifies that it is *the microorganism* that has protein hydrolysis potency (i.e., proteases, etc.). The specification at page 11, lines 12-19 further supports this position. Accordingly, Applicants submit that no amendment is necessary.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

Applicants submit that the present application is now in condition for allowance.

Early notice to this effect is earnestly solicited.

Respectfully submitted,

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